UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,883	04/13/2000	Michael I. Watkins	2558B-061300US	7641

7590 04/28/2005

M. HENRY HEINES
TOWNSEND AND TOWNSEND CREW LLP
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,883	WATKINS ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *23-25,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-22 and 26-28* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response filed 5/26/04 is acknowledged and has been entered. Claims 23-25, 29 and 30 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-30 are pending. Claims 1-22 and 26-28 are under examination

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-2, 7-15, and 18-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins et al. (WO 99/26067) in view of Dietzen (US 5,795,789) and in further view of Weckermann (WO 95/02824) for reasons of record.

3. Claims 20-22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins et al. (WO 99/26067) in view of Dietzen (US 5,795,789) and in further view of Weckermann (WO 95/02824) as applied to claims 1-2, 7-15, and 18-19 above, and further in view of Frengen (US 5,723,346) for reasons of record.

4. Claims 3 and 16-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins et al. (WO 99/26067) in view of Dietzen (US 5,795,789) and in further view of Weckermann (WO 95/02824) as applied to claims 1-2, 7-15, and 18-19 above, and further in view of Smith et al. (US 4,332,784) for reasons of record.

5. Claims 4-5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins et al. (WO 99/26067) in view of Dietzen (US 5,795,789) and in further view of Weckermann (WO 95/02824) as applied to claims 1-2, 7-15, and 18-19 above, and further in view Frieden et al. (J. Biol. Chem. (1948), 176, 155-63) and Block et al. (J. Med. Chem. (1976), 19(8), 1067-9) for reasons of record.

Response to Arguments

6. Applicant's arguments filed 5/28/04 have been fully considered but they are not persuasive.

A) Applicant argues that the inventorship of the present application has been changed to add Richard Edwards as an inventor; hence, WO 99/26067 represents the joint work of Watkins and Edwards and comments contained therein about the applicability of the assay for testing thyroid conditions represent work of inventors of the instant application. Applicant contends that being that WO 99/26067 is published less than one year prior to the filing of this Application, it does not qualify as prior art under 35 USC 102 (a).

In response, Michael Watkins, Suknan Chang, Renato Del Rosario, Patricia Miranda, Timothy Knight, and Richard Edwards are all listed as inventors of the present application. Since the instant application has an inventive entity that is different from that of WO 99/26067, it is being maintained that the instant invention has been invented by another or by others, under the provisions of 35 USC 102 (a) which states that "A person shall be entitled to a patent unless -(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

B) Applicant argues that the combination of Watkins et al. with each one of Dietzen, Weckermann, and Smith do not render obvious the claimed invention because each of the secondary references lack relevance to the disclosure of WO 99/26067 and the claimed invention. Applicant exemplifies Dietzen as only being directed to providing a single liquid standard or calibration solution for use in multi-analyte assays but do not disclose how to carry out such study. Applicant further exemplifies Smith et al. as being

only directed to dual-isotope technique in a competitive assay using two thyroid markers and again do not disclose the relevant process that are claimed in WO 99/26067 and the claimed invention. Applicant contends that the instant application describe a multi-stage process for conducting assay for four or five different specific analytes simultaneously, using specifically coated particles, specifically defined labels, and specific analytical techniques.

In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Watkins et al. is relied upon for the teaching of a multiplex flow assay for simultaneous determination of biological markers indicative of thyroid function using solid magnetic particles which are classifiable by flow cytometry into discrete groups according to distinguishable characteristics, differentiation parameters, and specific antibodies or antigens (assay reagents) which bind in a selective manner. Watkins et al. teach that multiple combination assays can be performed on the single patient sample; thus combining competitive, sandwich, immunometric, and serological assays such as assays for TSH or total T_4. Dietzen is relied upon only for the teaching that thyroid function study requires accurate assessment of all of thyroid markers, i.e. TSH, T_3, and T_4 using specific antibodies thereto, in a simultaneous multiple thyroid related-analyte binding assay. Smith et al. is only relied upon for providing that assays for two of TSH, T_3, T_4, and TBG using antibodies thereto, play important role as biological markers in assessing thyroid

function. In other words, since Watlkins et al. has disclosed all of the method steps required for the claimed process, but only fail to disclose use of other thyroid markers in the simultaneous assay determination for thyroid function, and T_3 has been shown by Dietzen to be another thyroid marker, and TBG has been shown by Smith to be another thyroid marker, then it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the teaching of Dietzen and Smith into the method of Watkins because Watkins specifically taught that his method allows for simultaneous multiple determination and differentiation of physiologically related biological markers such as TSH, T_4, T_3, hTPO, and TBG as taught by Dietzen and Smith, all of which can contribute individually and cumulatively, to the assessment of thyroid function.

Allowable Subject Matter

7. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
January 31, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
2/5/05